Foreword

In October 2005, the General Conference of UNESCO adopted by acclamation the Universal Declaration on Bioethics and Human Rights. For the first time in the history of Bioethics, Member States committed themselves and the international community to respect and apply the fundamental principles of bioethics set forth within a single text.

In dealing with ethical issues raised by medicine, life sciences and associated technologies as applied to human beings, the Declaration, as reflected in its life, anchors the principles it enunciates in the rules that govern respect for human dignity, human rights and fundamental freedoms. By advancing bioethics in international human rights and by ensuring respect for the life of human beings, the Declaration recognizes the interrelation between ethics and human rights in the specific field of bioethics.

Together with the Declaration, the General Conference of UNESCO adopted a resolution which calls upon Member States to make every effort to give effect to the principles set out in the Declaration and invites me to take appropriate steps to ensure the follow-up to the Declaration, including its widest possible dissemination.

This brochure constitutes a first tool for the dissemination of the Declaration and is aimed at contributing significantly to knowledge of the Declaration worldwide and to understanding of the principles set out therein, so that human beings everywhere can benefit from the advances of science and technology within the framework of respect for human rights and fundamental freedoms.

Koichiro Matsuura

United Nations Educational, Scientific and Cultural Organization
Division of Ethics of Science and Technology
Social and Human Sciences Sector
1, rue Miollis – 75732 Paris Cedex 15 - France
www.unesco.org/ethics
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Koichiro Matsuura
Director-General
Universal Declaration on Bioethics and Human Rights

Introduction

The General Conference, 

Conscious of the unique capacity of human beings to reflect upon their own existence and on their environment, to perceive injustices, to avoid danger, to assume responsibility to seek cooperation and to inhibit the moral sense that gives expression to ethical principles,

Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,

Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due regard to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Realizing that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity’s response to the ever-increasing dilemmas and controversies that science and technology present for human and for the environment,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration on Human Genocide and Human Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003,


Also noting international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, which was adopted in 1997 and entered into force in 1999, together with its Additional Protocols, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1983, 1989, 1996 and 2000 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences, adopted in 1992 and amended in 1993 and 2002,

Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law,

Recalling the Constitution of UNESCO adopted on 16 November 1945,

Considering UNESCO’s role in identifying universal principles based on shared ethical values to guide scientific and technological development and social transformation in order to identify emerging challenges in science and technology taking into account the responsibility of the present generations towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data and taking account not only of the current scientific context but also of future developments,

Aware that human beings are an integral part of the biosphere, with an important role in protecting one another and other forms of life, in particular animals,

Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Recognizing that health does not depend solely on scientific and technological research developments but also on psychological and cultural factors,

Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole,

Bear in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary to humankind and, in this sense, the free exercise of human rights and fundamental freedoms,

Also bearing in mind that a person’s identity includes biological, psychological, social, cultural and spiritual dimensions,

Recognizing that unethical scientific and technological conduct has had a particular impact on indigenous and local communities,

Convinced that moral sensibility and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments,

Considering the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the elevation of humanity,

Recognizing that an important way to evaluate social realities and achieve equity is to pay attention to the position of women,

Shrewing the need to reinforce international cooperation in the field of bioethics, taking into account, in particular, the special needs of developing countries, indigenous communities and vulnerable populations,

Considering that all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research,

Proclaims the principles that follow and adopts the present Declaration.

Universal Declaration on Bioethics and Human Rights

In October 2005, the General Conference of UNESCO

* Adapted by acclamation on 19 October 2005 by the 33rd session of the General Conference of UNESCO
Universal Declaration on Bioethics and Human Rights*

Foreword

In October 2005, the General Conference of UNESCO adopted the Universal Declaration on Bioethics and Human Rights

Universal Declaration on Bioethics and Human Rights*

annexed to the Marrakesh Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).


Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law.

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Also bearing in mind that a person’s identity includes biological, psychological, social, cultural and spiritual dimensions.

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Convinced that moral sensibility and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments.

Considering the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the benefit of humanity.

Recognizing that an important way to evaluate social realities and achieve equity is to pay attention to the position of women.

Stressing the need to reinforce international cooperation in the field of bioethics, taking into account, in particular, the special needs of developing countries, indigenous communities and vulnerable populations.

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International Declaration on Bioethics and Human Rights

[Signature]
Universal Declaration on Bioethics and Human Rights

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Universal Declaration on Bioethics and Human Rights

In October 2005, the General Conference of UNESCO, meeting in Paris, at the 33rd session of its General Conference, adopted the following Declaration by acclamation.

For immediate release

The General Conference of UNESCO met in Paris, at the 33rd session of its General Conference, and adopted, by acclamation, the following Declaration on Universal Declaration on Bioethics and Human Rights:...
Aims

1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.
2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2

The aims of this Declaration are:
(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;
(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;
(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with internationally recognized human rights;
(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while fostering the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;
(e) to foster multidisciplinary and pluralistic dialogue about bioethical issues across all stakeholders and within society as a whole;
(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of new knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
(g) to safeguard and promote the interests of the present and future generations;
(h) to underpin the importance of biodiversity and its conservation as a common concern of humankind.

Principles

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected:

Article 3

Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.
2. The interests and welfare of the individual should have priority over the interest of science or society.

Article 4

Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5

Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising their autonomy, special measures are to be taken to protect their rights and interests.

Article 6

Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free, informed and consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withheld by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards, and only for the purpose of protecting human life or for the purpose of this Declaration, in particular Article 27, and international human rights law.
3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement in the consent of a community leader or other authority substitute for an individual’s informed consent.

Article 7

Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:
(a) for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process related to that consent, as well as of that withdrawal consent.
(b) research should only be carried out in the case of a person’s best interest health benefit should only be undertaken by way of exception, with the utmost prudence, exposing the person to only a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual’s human rights. Refusal of such persons to take part in research should be respected.

Article 8

Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability shall be taken into account. Individuals and groups of special vulnerability shall be protected and the personal integrity of such individuals respected.

Article 9

Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information shall be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than for which it was collected or conserved, to consistent with international law, in particular international human rights law.

Article 10

Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11

Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12

Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism shall be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 13

Solidarity and cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

Article 14

Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments at all levels of society.
2. Taking into account that the enjoyment of the highest attainable standard of health is a universal right of every human being without distinction of race, sex, religion, political belief, economic or social condition, progress in science and technology should advance:
(a) to promote health and wellness and social justice, and to prevent illness and injury, and to support and maintain health and well-being;
(b) to provide equitable access to medical, scientific and technological developments and to the greatest possible flow and the rapid sharing of new knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries; and
(c) to enhance the recognition of the importance of biodiversity and its conservation as a common concern of humankind.

Article 15

Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
(a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
(b) access to quality health care;
(c) provision of new diagnostic and therapeutic modalities or products stemming from research;
(d) support for health services;
(e) access to scientific and technological knowledge;
(f) capacity building facilities for research purposes;
(g) other forms of benefit consistent with the principles set out in this Declaration.
2. Benefits should not constitute improper inducements to participate in research.

Article 16

Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17

Protection of the environment, the biosphere and biodiversity

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

Application of the principles

Article 18

Decommissioning and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted in a particular declaration of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.
2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.
3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Promotion of the Declaration

Article 19

Ethics committees

Independent, multidisciplinary and pluralistic ethics committees should be established, promoted and supported at the appropriate level in order to:
(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;
(b) provide advice on ethical problems in clinical settings;
(c) assess and promote ethical and legal standards;
(d) make recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;
(e) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20

Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21

Transnational practices

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in States, is consistent with the principles set out in this Declaration.
2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the States in which the funding is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.
3. When research is carried out in response to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.
4. When negotiating research agreements, terms for collaboration and agreement on the benefits of research should be established with equal participation by those parties to the negotiation.
5. States should take appropriate measures, both at the national and international levels, to combat bio-terrorism and conflicts in the form of terror and in the form of disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 22

Role of States

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.
2. States should encourage the establishment of independent, multidisciplinary and pluralistic ethics committees, as set out in Article 19.

Final provisions

Article 23

Bioethics education, training and information

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.
2. States should promote the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 24

International cooperation

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.
2. States should coordinate international cooperation. States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.
3. States should respect and promote solidarity between and among States, as well as between individuals, families, groups and communities, with special regard for those who are disadvantaged, by disease or disability, or other personal, societal or environmental conditions and those with the most limited resources.

Article 25

Follow-up action by UNESCO

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).
2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

Nothing in this Declaration may be interpreted as implying for any State, group or person any obligation to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.
Aims

1. FNR

2. The aims of this Declaration are:
   (a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;
   (b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private.

2. Arts

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising their autonomy, special measures are to be taken to protect their rights and interests.

2. Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free, informed and consented to the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withheld by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards in the field of interested and in the context of national human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement in the consent of a community leader or other authority substitute for an individual’s informed consent.

2. Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent.

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, consent should be involved to the greatest extent possible in the decision-making process and actually be obtained, as well as that of withdrawing consent.

(b) research should only be carried out for her direct and health benefit, subject to the authorization and the protective prescriptions by law, and if there is no research alternative of comparable effectiveness with research participants able to consent and which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost prudence, exposing the person to only a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual’s health. Refusal of such persons to participate in research should be respected.

2. Ethics committees

Independent, multidisciplinary and plural ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

2. Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

2. Transnational practices

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in one or more States, is consistent with the principles set out in this Declaration.

2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

3. Health research related to the needs of host countries, and the importance of research contributing to the alleviation of urgent and global health problems should be recognized.

4. When negotiating or entering agreements, terms for collaboration and agreement on the benefits of research should be established with equal participation by those parties to the negotiation.

5. States should take appropriate measures, both at the national and international levels, to promote broader patient and public involvement in the processes of clinical care, the regulation of services, the strategy for health research, and the development of new knowledge. The benefits of research should be shared with those groups of people who are directly or indirectly affected by health research.

2. Promotion of the Declaration

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising their autonomy, special measures are to be taken to protect their rights and interests.

2. Role of States

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the sphere of education, training and public information.

2. States should encourage the establishment of independent, multidisciplinary and plural ethics committees, as set out in Article 19.

2. Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

2. Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for any purpose other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

2. Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

2. Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

2. Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism shall be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

2. Solidarity and cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

2. Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments at all levels of society.

2. Taking into account that the enjoyment of the highest attainable standard of health is a universal right, the Declaration recognizes the right of everyone being without distinction of race, gender, religion, political belief, economic or social condition, progress in science and technology should advance:

(a) to access health care and essential medicines, especially for the health of children and women, because health is life itself and must be considered to be a social and human good;

(b) to adequate nutrition and water;

(c) improvement of living conditions and the environment;

(d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;

(e) reduction of poverty and illiteracy.

2. Bioethics education, training and information

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.

2. States should promote the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

2. International cooperation

1. States shall promote international cooperation. States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

2. States shall respect and promote solidarity between and among States, as well as between individuals, families, groups and communities, with special regard for those groups especially vulnerable to disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

2. Follow-up action by UNesco

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).

2. UNesco shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

Final provisions

2. InternationaL and complemenitary of the principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and integrated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

2. Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

2. Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person the right to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.
Aims of this Declaration

The aims of this Declaration are:

1. to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;
2. to guide the actions of individuals, groups, communities, institutions and corporations, public and private.

Social responsibility and health

General provisions

Article 1 Scope

1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.

2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2 Aims

The aims of this Declaration are:

(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;
(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;
(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;
(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;
(e) to foster multidisciplinary and pluralist dialogue about bioethical issues across all disciplines and within society as a whole;
(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and rapid sharing of such knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
(g) to safeguard and promote the interests of the present and future generations;
(h) to underline the importance of biodiversity and its conservation as a common concern of humanity.

Principles

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected.

Article 3 Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.

2. The interests and welfare of the individual should have priority over the interest in science or society.

Article 4 Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibly for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising their autonomy, special measures are to be taken to protect their rights and interests.

Article 6 Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free, and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards, and the protection of human rights, as specified in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual’s informed consent.

Article 7 Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent.

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with national law. Consent of the person concerned should be involved to the greatest extent possible in the decision-making process, as well as that of withdrawing consent.

(b) research should only be carried out for its direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with respect to patients’ abilities to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual’s health rights. Refusal of such persons to take part in research should be respected.

Article 8 Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 9 Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed other than for the reasons for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 10 Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated fairly and equitably.

Article 11 Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12 Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 13 Solidarity and cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

Article 14 Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments of all sectors of society.

2. In taking account that the enjoyment of the highest attainable standard of health is a fundamental right of every human being without distinction of race, sex, religion, political belief, economic or social condition, progress in science and technology should advance:

(a) to improve health and welfare and to reduce disparities between those living in developed and developing countries;
(b) to promote health and health services to the utmost extent practicable, and to prevent, detect and treat disease, pain and disablement, to secure quality health care, and to ensure that the health of nations is a state monopoly;
(c) to ensure that the responsibility for the promotion of health is shared equally by individuals and all segments of society, and that health is a public and personal responsibility and is promoted by all segments of society.

Article 19 Ethics committees

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20 Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21 Transnational practices

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in the territory of another State, is consistent with the principles set out in this Declaration.

2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

3. If research is health-related and responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.

4. When negotiating research agreements, terms for collaboration and agreement on the benefits of research should be established with equal participation by those parties to the negotiation.

5. States should take appropriate measures, both at the national and international levels, to promote international cooperation, including training in bioethics, research, monitoring and evaluation.

6. States should promote the participation of international and regional intergovernmental organizations and international, regional and national nongovernmental organizations in this endeavour.

Article 23 Biosafety education, training and information

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster biosafety education and training at all levels as well as to encourage information and knowledge dissemination programmes about biosafety.

2. States should promote the participation of international and regional intergovernmental organizations and international, regional and national nongovernmental organizations in this endeavour.

Article 24 International cooperation

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.

2. States should promote international cooperation. States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

3. States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those found to be vulnerable by reason of disease or disability, or other personal, societal or environmental conditions and those with the most limited resources.

Article 25 Follow-up action by UNESCO

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should take the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).

2. UNESCO shall reaffirm its commitment to dealing with biosafety and to promoting collaboration between IGBC and IBC.

Final provisions

Article 26 Internationality and complementarity of the principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and not only confined to the legal title of this document. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

Article 27 Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28 Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person the right to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.
Article 1

Scope

1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.
2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2

Aims

The aims of this Declaration are:

(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;
(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private; and
(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law.

Article 3

Principles

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected:

1. Human dignity, human rights and fundamental freedoms are to be fully respected.
2. The integrity and welfare of the individual should have priority over the interest of science or society.

Article 4

Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5

Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who may not be capable of exercising an autonomous, special measures are to be taken to protect their rights and interests.

Article 6

Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards governing the protection of human rights.
3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. No case should a collective community agreement in the consent of a community leader or other authority substitute for an individual’s informed consent.

Article 7

Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. The person concerned should be involved to the greatest extent possible in the decision-making process with the consent of the person, as far as that of withdrawing consent.
(b) research should only be carried out for or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research’s participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the promotion of the individual’s human rights. Refusal of such persons to take part in research should be respected.

Article 8

Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 9

Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 10

Equity, justice and equality

The fundamental equality of all humans in dignity and rights is to be respected so that they are treated fairly and equally.

Article 11

Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12

Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 13

Solidarity and cooperation

Solidarity among humans and international cooperation towards that end are to be encouraged.

Article 14

Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments at all levels of society.
2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political, belief, economic or social condition, progress in science and technology should advance:
   (a) to improve the quality of health care and essential medicines, especially for the health of women and children, because health is a life right and must be considered to be a social and human good;
   (b) to adapt to the economic and social conditions of the country;
   (c) to improve the living conditions and the environment;
   (d) to encourage the planning and the exclusion of persons on the basis of any grounds;
   (e) to reduce poverty and illiteracy.

Article 15

Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and in the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
   (a) any special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
   (b) access to quality health care;
   (c) provision of new diagnostic and therapeutic modalities; products stemming from research;
   (d) support for health services;
   (e) access to scientific and technological knowledge;
   (f) capacity-building facilities for research purposes;
   (g) other forms of benefit consistent with the principles set out in this Declaration.
2. Benefits should not constitute improper inducements to participate in research.

Article 16

Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17

Protection of the environment, the biosphere and biodiversity

Due regard is to be given to the interaction between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

Article 18

Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular decisions on all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.
2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.
3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 19

Ethics committees

Independent, multidisciplinary and plural ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;
(b) provide advice on ethical problems in clinical settings;
(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;
(d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20

Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21

Transnational practices

1. States, public and private institutions, and professional associations associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part on behalf of a State, is consistent with the principles set out in this Declaration.
2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.
3. Health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.
4. When negotiating research agreements, terms for collaboration and agreement on the benefits of research should be established with explicit participation by those parties to the negotiation.
5. States should take appropriate measures, both at the national and international levels, to protect the health and well-being of the populations and ensure that the principles set out in this Declaration are respected.

Article 22

Role of States

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.
2. States should encourage the establishment of independent, multidisciplinary and plural ethics committees, as set out in Article 19.
Aims
Social responsibility and health
Pro
Human dignity and human rights
Denial of acts contrary to human dignity and its conservation as a common concern of humankind

Principles

Within the scope of this Declaration, in decisions or practices taken or carried out by those whom it is addressed, the following principles are to be respected.

Article 3 Human dignity and human rights
1. Human dignity, human rights and fundamental freedoms are to be fully respected.
2. The interests and welfare of the individual should have priority over the rule of science or society.

Article 15 Sharing of benefits
1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
   (a) special and substantial assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
   (b) access to quality health care;
   (c) provision of new and diagnostic therapies, medicinal products or devices stemming from research;
   (d) support for health services;
   (e) access to scientific and technological knowledge;
   (f) capacity-building facilities for research purposes;
   (g) other forms of benefit consistent with the principles set out in this Declaration.
2. Benefits should not be contributory inducements to participate in research.

Article 16 Protecting future generations
The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17 Protection of the environment, the biosphere and biodiversity
Due regard is to be given to the intersection between human beings and other forms of life, to the importance of appropriate access and utilization of biocultural and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

Application of the principles

Article 18 Decision-making and addressing bioethical issues
1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular decisions on all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.
2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.
3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 4 Benefit and harm
In advancing and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 Autonomy and individual responsibility
The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising their autonomy, special measures are to be taken to protect their rights and interests.

Article 6 Consent
1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free, informed and consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withheld by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards. Such exceptional cases of research shall be part of the present text in this Declaration, in particular in Article 27, and international human rights law.
3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement in the consent of a community leader or other authority substitute for an individual’s informed consent.

Article 7 Persons without the capacity to consent
In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent.
(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with the law. However, the person concerned should be involved to the greatest extent possible in the decision-making process for the consensus, as well as that of withholding consent.
(b) research should only be carried out for her direct health benefit, subject to the authorization and the protective conditions prescribed by law. and no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden.
(c) if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual’s rights. Refusal of such persons to take part in research should be respected.

Article 19 Ethics committees
Independent, multidisciplinary and pluridisciplinary ethics committees should be established, promoted and supported at the appropriate level in order to:
(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;
(b) provide advice on ethical problems in clinical settings;
(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;
(d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20 Risk assessment and management
Appropriate assessment and adequate management of risk related to medical, life sciences and associated technologies should be promoted.

Article 21 Transactional practices
1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in States, is consistent with the principles set out in this Declaration.
2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.
3. Health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.
4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.
5. States should take appropriate measures, both at the national and international levels, to ensure that the information and knowledge resulting from research lead to no identifiable harm to patients, research participants and other affected individuals.

Article 22 Role of States
1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the sphere of education, training and public information.
2. States should encourage the establishment of independent, multidisciplinary and pluridisciplinary ethics committees, as set out in Article 19.

Article 23 Bioethics education, training and information
1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavor to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.
2. States should promote the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 24 International cooperation
1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.
2. States should promote international cooperation. States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.
3. States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those who are disabled, sick, disadvantaged by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 25 Follow-up action by UNESCO
1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).
2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

Final provisions

Article 26 Interpretation and complementarity of the principles
This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

Article 27 Limitations on the application of the principles
If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28 Denial of acts contrary to human rights, fundamental freedoms and human dignity
Nothing in this Declaration may be interpreted as implying for any State, group or person, the right to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.
Aims

1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.

2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2

Aims

The aims of this Declaration are:

(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;
(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;
(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;
(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;
(e) to foster multidisciplinary and pluralistic dialogue about bioethical issues across all levels of society and within society as a whole;
(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
(g) to safeguard and promote the interests of the present and future generations;
(h) to underline the importance of biodiversity and its conservation as a common concern of humankind.

Principles

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected:

Article 3

Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.

2. The interests and welfare of the individual should have priority over the role of science or society.

Article 15

Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and into the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

(a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;

(b) access to quality health care;

(c) provision of new and diagnostic therapeutic modalities or products stemming from research;

(d) capacity-building facilities for research purposes;

(e) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not be constituted improper inducements to participate in research.

Article 16

Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17

Protection of the environment, the biosphere and biodiversity

Due regard is to be given to the interaction between human beings and other forms of life, to the importance of appropriate access and utilization of biocultural and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

Application of the principles

Article 18

Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular decisions on all conflicts of interest, and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 4

Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5

Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising their autonomy, special measures are to be taken to protect their rights and interests.

Article 6

Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free, informed and consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards laid down in international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement in the consent of a community leader or other authority substitute for an individual’s informed consent.

Article 7

Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent.

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. The person concerned should be involved to the greatest extent possible in the decision-making process with respect to consent, as well as of withdrawing consent.

(b) research should only be carried out for her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the benefit of health of other persons in the same category, subject to the conditions prescribed by law and compatible with the promotion of the individual’s health rights. Refusal of such persons to take part in research should be respected.

Ethics committees

Independent, multidisciplinary and pluralistic ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20

Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21

Transnational practices

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part outside of a State, is consistent with the principles set out in this Declaration.

2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

3. States should ensure that research is responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.

4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those parties to the negotiation.

5. States should take appropriate measures, both at the national and international levels, to prevent exploitation of human beings in the context of transnational research activities.

Article 22

Role of States

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.

2. States should encourage the establishment of independent, multidisciplinary and pluralistic ethics committees, as set out in Article 19.

Article 23

Bioethics education, training and information

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.

2. States should promote the participation of international and regional intergovernmental organizations and international, regional and non-governmental organizations in this endeavour.

Article 24

International cooperation

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.

2. States should promote international cooperation. States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

3. States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those whose affiliation is by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 25

Follow-up action by UNESCO

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).

2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

Final provisions

Article 26

Interrelation and complementarity of the principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

Article 27

Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28

Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person, the right to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.
Foreword

In October 2005, the General Conference of UNESCO adopted by acclamation the Universal Declaration on Bioethics and Human Rights. For the first time in the history of Bioethics, Member States committed themselves and the international community to respect and apply the fundamental principles of bioethics set forth within a single text.

In dealing with ethical issues raised by medicine, life sciences and associated technologies as applied to human beings, the Declaration, as reflected in its title, anchors the principles it endorses in the rules that govern respect for human dignity, human rights and fundamental freedoms. By enshrining bioethics in international human rights and by ensuring respect for the life of human beings, the Declaration recognizes the interconnection between ethics and human rights in the specific field of bioethics.

Together with the Declaration, the General Conference of UNESCO adopted a resolution which calls upon Member States to make every effort to give effect to the principles set out in the Declaration and invites me to take appropriate steps to ensure the follow-up to the Declaration, including its widest possible dissemination.

This brochure constitutes a first tool for the dissemination of the Declaration and is aimed at contributing significantly to knowledge of the Declaration worldwide and to understanding of the principles set out therein, so that human beings everywhere can benefit from the advances of science and technology within the framework of respect for human rights and fundamental freedoms.

Koichi Matsuura

United Nations Educational, Scientific and Cultural Organization
Division of Ethics of Science and Technology
Social and Human Sciences Sector
1, rue Mollien - 75732 Paris Cedex 15 - France
www.unesco.org/ethics
SHS/EST/BIO/06/06
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